

122.4±178.3 mg/dl,  $p=0.006$ ), pre-PCI minimal lumen diameter was smaller ( $0.19\pm0.30$ mm vs.  $0.32\pm0.36$ mm,  $p=0.041$ ), pre-PCI diameter stenosis was higher ( $93.9\pm9.5\%$  vs  $89.6\pm11.5\%$ ,  $p=0.037$ ), pre PCI TIMI flow was lower (pre-PCI TIMI flow non-3; 77.8% vs. 59.3%,  $p=0.038$ ), and post-PCI diameter stenosis was higher ( $14.6\pm5.8\%$  vs.  $11.6\pm5.0\%$ ,  $p=0.004$ ). Multivariate analysis revealed peak CK-MB and EF were independent predictor of TP. During three years of follow up, major adverse cardiac events (MACE; target vessel revascularization, myocardial infarction, death) were not different in TP + and TP – groups (11.1% vs. 16.7%,  $p=0.404$ ).

**Conclusions:** Despite of minor angiographic difference, TP was not associated with three-year MACE in patients with primary coronary stent implantation due to STEMI.

# TCT-560

## Randomized Serial Optical Coherence Tomographic Evaluation of The Lesions Following Biolimus-A9-eluting versus Sirolimus-eluting stents; SEVEN OCT trial

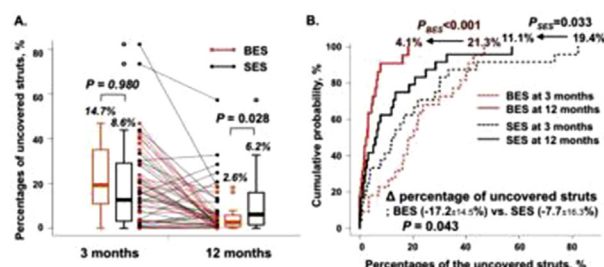
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**Background:** No randomized studies have been conducted to investigate serial changes of optical coherence tomography (OCT) findings following biolimus-A9-eluting stents (BES) vs. sirolimus-eluting stents (SES) implantation.

**Methods:** A total of 60 patients fulfilling study criteria were randomly assigned into BES (n=30) and SES (n=30) implantation. Of these, serial OCT evaluation at post-procedure, 3, and 12 months was performed in 46 patients [BES (n=22) and SES (n=24)] and OCT findings were compared according to the types of stents and followed time intervals. The primary endpoint was the percentage of uncovered struts (ratio of uncovered struts to total struts in all cross-sections with 0.2-mm interval) at 3 and 12 months and the changes ( $\Delta$ ) of percentages between 3-12 months.

**Results:** Although the percentages of uncovered struts at 3 months were not significantly different between two stents, BES compared to SES showed a significantly higher percentage of uncovered struts on 12-month OCT without significant difference of neointimal thickness (See Figure A). Through serial OCT evaluation, both stents significantly increased strut coverage from 3 to 12 months. However, BES showed a greater  $\Delta$  percentage of uncovered struts between 3-12 months than SES (See Figure B).



**Conclusions:** In this randomized serial OCT study, both DESs still showed the incomplete strut coverage at 3 months but BES compared to SES showed a significantly lower prevalence of uncovered struts at 12 months by superior coverage from 3 to 12 months.

# TCT-561

## Comparison Of Stent Axial Integrity In First- Versus Second-Generation Drug-Eluting Stents: Insights From An Intravascular Ultrasound Analysis

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**Background:** Longitudinal stent deformation (LSD) is a recently reported complication of coronary intervention. However, to date, the axial integrity of stents has not been systematically examined. This study aimed to assess the rate of LSD after implantation utilizing intravascular ultrasound (IVUS).

**Methods:** A total of 218 drug-eluting stents (DES) of 197 patients with coronary artery disease who underwent IVUS after implantation for de novo lesions were included: 32.1% sirolimus-eluting stents (SES); 15.6% paclitaxel-eluting stents (PES); 22.9% cobalt-chromium everolimus-eluting stents (CC-EES); and 29.4% platinum-chromium everolimus-eluting stents (PC-EES, Element platform). Stent length was

determined using automatic pullback of an IVUS catheter. The absolute value of the difference in length [IVUS-measured stent length – labeled stent length] (mm), and the absolute value of the relative difference in length [(IVUS-measured stent length – labeled stent length) divided by labeled length] (%) were analyzed.

**Results:** There was no significant difference with regards to the absolute and relative differences in stent length among groups. The absolute relative difference of >5% was the lowest in the SES group compared to the other groups. Significant (>15%) absolute value of the relative difference in stent length was low and similar among groups. (Table)

IVUS findings					
	Cypher (n=70)	TAXUS (n=34)	Xience/ Promus (n=50)	Promus Element (n=64)	P value
Absolute value of difference in length [IVUS-measured length-labeled length] (mm)	1.0±0.7	1.0±0.7	1.0±0.7	0.9±0.6	0.965
Absolute value of relative change in length [(IVUS-measured length-labeled length)/labeled length] (%)	4.9±3.8	6.2±4.5	5.7±3.6	6.0±4.7	0.386
Absolute relative difference of >5% (%)	34.3	58.8	54.0	51.6	0.048
Absolute relative difference of >15% (significant difference) (%)	2.9	5.9	4.0	4.7	0.896

**Conclusions:** This IVUS analysis proved that there are no significant differences in axial stent integrity between first- and second-generation DES and among second-generation DES. The anecdotal reports of longitudinal deformation are unsubstantiated in contemporary clinical practice.

# TCT-562

## Impact of Target Lesion Coronary Calcification on Stent Expansion: An Optical Coherence Tomography Study

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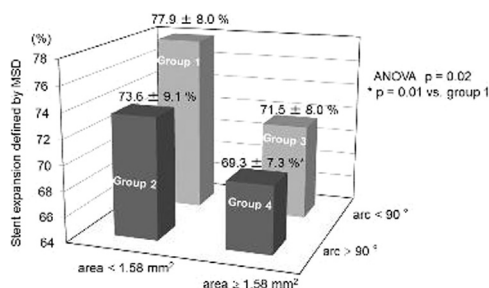
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**Background:** Stent underexpansion is still a concern as a cause of drug-eluting stent (DES) failure. Although the amount of coronary calcification is considered as a contributing factor for stent under expansion, a previous intravascular ultrasound (IVUS) study failed to demonstrate relation between stent expansion and coronary calcification. Optical coherence tomography (OCT) offers better quantitative assessment of coronary calcium than IVUS and therefore may have potential to predict stent expansion. Thus, the purpose of this study was to investigate whether stent expansion could be predicted by coronary calcification assessed by OCT.

**Methods:** A total of 51 de novo native coronary artery lesions from 44 patients treated by single 2nd generation DES were enrolled. Prior to stent deployment, arc of calcium and area of calcium at the maximal calcification site within the target lesion were measured using OCT. After successful stent implantation, OCT imaging was repeated

to assess minimal stent diameter and area (MSD and MSA). Stent expansion was defined as MSD (or MSA) divided by the values predicted by the manufacturers' compliance charts. Patients were divided into 4 groups according to the median values of arc and area of calcium.

**Results:** Mean stent expansion was  $73.3 \pm 8.7\%$  for MSD and  $65.2 \pm 12.0\%$  for MSA. Stent expansion defined by MSD was significantly different among the groups ( $p = 0.02$ ) (Figure). Similar trend was observed for stent expansion defined by MSA ( $p = 0.16$ ).



**Conclusions:** Stent expansion of the 2nd generation DESs may be predicted by the amount of target lesion calcification assessed by OCT.

#### TCT-563

**Fusion of intravascular ultrasound and X-ray angiography does not allow accurate evaluation of the endothelial shear stress patterns and neointimal distribution after bioresorbable scaffold implantation. A comparison with optical coherence tomography-derived reconstructions**

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**Background:** To examine the endothelial shear stress (ESS) patterns, the neointimal distribution and the relation between ESS and neointimal thickness (NT) in models derived from the integration of frequency domain optical coherence tomographic (FD-OCT) and coronary angiographic data and compare these estimations with those computed in the traditional reconstructions obtained by the fusion of intravascular ultrasound (IVUS) and coronary angiography.

**Methods:** Six segments implanted with an Absorb Bioresorbable Vascular Scaffold (Absorb BVS) that were investigated with FD-OCT and IVUS examination at baseline and 6 or 12 months follow-up were included. The IVUS and OCT data acquired at follow-up were fused separately with the angiographic data to reconstruct the luminal surface at baseline and follow-up. Blood flow simulation was performed on the baseline IVUS-based and OCT-based models and computational fluid dynamics techniques were implemented to assess the ESS and the association between the ESS and the measured NT at follow-up.

**Results:** The IVUS-based models appeared to underestimate the neointima tissue ( $0.67 \pm 0.59$  mm<sup>3</sup> vs.  $15.14 \pm 5.63$  mm<sup>3</sup>,  $P = 0.001$ ) compared to the FD-OCT-based reconstructions. Flow recirculation zones were detected in the FD-OCT-based reconstructions and the ESS values were lower compared to the IVUS-based models ( $1.29 \pm 0.66$  Pa vs.  $1.87 \pm 0.66$  Pa,  $P = 0.030$ ). These differences should be attributed to the poor resolution of IVUS that did not allow visualization of the protruded struts. A statistically significant inverse correlation was noted between the logarithmic ESS at baseline and the NT at follow-up in all the FD-OCT-based models which was higher than the correlation reported in 5 of the 6 IVUS-derived models (mean correlation coefficient:  $-0.52 \pm 0.19$  vs.  $-0.10 \pm 0.04$ ,  $P = 0.028$ ).

**Conclusions:** It appears that the models derived by the fusion of IVUS and coronary angiography cannot provide enough detail and are incapable of assessing the micro-environment and its effect on neointima formation following an Absorb BVS implantation. FD-OCT reconstruction appears superior to IVUS-based reconstructions and it should be preferred for studying the effect of ESS on neointimal proliferation.

#### TCT-564

**Implications of the local hemodynamic forces on vessel wall responses following drug-eluting bioresorbable vascular scaffold implantation: an optical coherence tomography analysis**

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**Background:** The aim of this study is to examine the implications of the local endothelial shear stress (ESS) on neointimal proliferation following an Absorb Bioresorbable Vascular Scaffold (BVS) implantation.

**Methods:** Twelve patients who had an Absorb BVS implantation in a stenotic, relatively straight arterial segment and who were investigated with serial optical coherence tomographic examination at baseline and 1 year follow-up were included in the current analysis. The optical coherence tomographic data acquired at follow-up were used to reconstruct the treated segment. Blood flow simulation was performed on the luminal surface at baseline defined by the Absorb BVS struts and the estimated ESS was related to the neointima thickness measured at 1 year follow-up.

**Results:** The protruded struts appeared to affect the ESS patterns. Low ESS and recirculation zones were noted between the struts areas and high ESS zones on the top of the struts. At baseline, 61% of the measured ESS were  $< 1$  Pa. At follow-up, the mean neointima thickness was  $113 \pm 45$   $\mu$ m while the percentage area obstruction was  $13.1 \pm 6.6\%$ . A weak but statistically significant inverse correlation was noted between baseline ESS and neointima thickness at 1 year follow-up in all studied segments (correlation coefficient range:  $-0.110$  to  $-0.620$ ). Mixed linear regression analysis between baseline ESS and neointima thickness at follow-up yielded a slope of  $-29$   $\mu$ m/Pa and a y-intercept of  $142$   $\mu$ m.

**Conclusions:** The hemodynamic micro-environment appears to regulate neointimal response following an Absorb BVS implantation. These findings underline the role of the ESS patterns on vessel wall healing and should be taken into consideration in the design of bioresorbable devices.

#### TCT-565

**OCT evaluation of the time course of vessel healing following implantation of new generation biodegradable polymer-coated and sirolimus-eluting cobalt-chromium coronary stent system (ALEX OCT Study).**

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**Background:** Biodegradable stent coatings are hoped to improve the vessel wall healing. ALEX is a new generation, biodegradable polymer-coated, sirolimus-eluting, cobalt-chromium coronary stent system.

**Methods:** A prospective, single arm, multi-centre registry enrolled 60 patients with de novo native coronary lesions treated with ALEX stent and examined the outcomes by quantitative coronary analysis (QCA) and optical coherence tomography (OCT) at multiple timepoints (3 subgroups of 20 patients each at 3, 6 and 12 months) to capture the time course of vessel healing. Stent strut coverage, stent apposition and neointimal proliferation were assessed by OCT. Safety endpoint was the composite of death, myocardial infarction, target lesion re-intervention (TLR) and stent thrombosis (ST) at 30 days and 12 month follow-up.

**Results:** At baseline, reference vessel diameter was  $2.85$  (IQR  $2.45$ ,  $3.17$ ) mm, lesion length was  $12.00$  (IQR  $9.67$ ,  $14.58$ ), minimal lumen diameter was  $1.02 \pm 0.40$  mm and percent diameter stenosis (%DS) was  $65 \pm 11.5$  by QCA. We have treated 31% of lesions type A/B1 and 69% of lesions type B2/C. Median stent diameter was  $3.0$  (IQR  $2.75$ ,  $3.50$ ) mm, stent length was  $15$  (IQR  $12$ ;  $20$ ) mm. Procedural device success rate was 98.7% with post-procedural %DS  $6.0$  (IQR  $2.0$ ;  $8.5$ ). QCA analysis revealed median late lumen loss (mm)  $0.035$  (IQR  $-0.047$ ,  $0.01$ ) at 3 months,  $0.17$  (IQR  $-0.01$ ,  $0.32$ ) at 6 months, and  $0.14$  (IQR  $0.07$ ,  $0.42$ ) at 12 months. The OCT analysis presented full strut coverage in 96% at 3 months, in 98% at 6 months, and 100% at 12 months. The rate of uncovered stent struts per section (RUST)  $> 0.3$  was 3.15% at 3 months, 1.74% at 6 months, and 0% at 12 months of follow-up, and the malapposition rate was 0.13%, 0.03% and 0.02%, respectively. There was one death (1.7%), one TLR (1.7%) and no definite ST at 12th months of follow-up.

**Conclusions:** Biodegradable polymer-coated, sirolimus-eluting ALEX stent appears to feature very favourable profile of arterial wall healing already at 3 months post